

## AMENDMENT AND RESPONSE UNDER 37 CFR § 1.116 – EXPEDITED PROCEDURE

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Filing Date: September 8, 2000

Dkt: 279.279US1

Title: IMPROVED RATE-ADAPTIVE THERAPY WITH AUTOMATIC LIMITING OF MAXIMUM PACING RATE

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Amendments to the Claims

Please amend the claims as follows:

1. (Previously Amended) A method for operating a rate-adaptive pacemaker wherein measured exertion levels in a patient are mapped to a sensor indicated rate by a rate response curve, comprising:

automatically determining the patient's maximum exercise capacity as defined by a long-term maximum exertion level by collecting maximum measured exertion levels over a specified period of time;

wherein the rate response curve is defined such that an exertion level corresponding to the patient's maximum exercise capacity would be mapped to a physiologically favorable maximum rate, MAR;

limiting the sensor indicated rate to a specified maximum sensor indicated rate MSR that is independent from the MAR; and,

increasing the MSR after a specified time period during which the long-term maximum exertion level is updated.

2. (Original) The method of claim 1 wherein the MSR is gradually increased to equal the MAR.

3. (Currently Amended) The method of claim 2 further comprising:

collecting daily maximum exertion levels;

periodically updating a long-term ~~maximal~~ maximum exertion level of the patient to equal a maximum among the collected daily maximum exertion levels during the specified time period; and,

adjusting a slope of the rate response curve in order for the updated long-term maximal exertion level to be mapped to the MAR.

4. (Original) The method of claim 3 wherein the collected daily maximum exertion levels are maximums among moving averages of the exertion levels measured during a day.

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5. (Previously Amended) The method of claim 3 wherein the rate response curve is a dual-slope curve where the slope changes from a low rate response factor to a high rate response factor at a heart rate breakpoint that is computed as a percentage of the patient's rate reserve.

6. (Original) The method of claim 5 wherein the rate response curve is adjusted by increasing or decreasing the low rate response factor.

7. (Previously Amended) The method of claim 5 wherein the high rate response factor is adjusted to map the patient's long-term maximum exertion level to the MAR.

8. (Original) The method of claim 5 wherein the slope of the rate response curve is adjusted with the heart rate breakpoint maintained as a fixed percentage of the rate reserve.

9. (Original) The method of claim 5 wherein the slope of the rate response curve is adjusted with the heart rate breakpoint maintained as a dynamic percentage of the rate reserve that changes in accordance with changes in the long-term maximum exertion level.

10. (Previously Amended) The method of claim 5 wherein a percentage of the patient's rate reserve used to compute the heart rate breakpoint is increased or decreased by the percentage increase or decrease, respectively, in the long-term maximum exertion level as a result of updating.

11. (Currently Amended) The method of claim 1 further comprising:  
collecting daily maximum exertion levels and daily maximum sensor indicated rates;  
computing weekly averages of the daily maximum exertion levels and sensor indicated rates;  
computing a sensor target rate as a function of the weekly average daily maximum exertion level and the patient's maximum exercise capacity as defined by the long-term maximum exertion level; and,

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periodically adjusting ~~the~~ a slope of the rate response curve in accordance with a difference between the weekly average maximum sensor indicated rate and the sensor target rate.

12. (Original) The method of claim 11 wherein the sensor target rate is computed as a mapping from a maximum exertion level to a percentage of the patient's maximum allowable heart rate.

13. (Previously Amended) The method of claim 12 wherein the maximum exertion level is mapped to the percentage of the patient's maximum allowable heart rate in accordance with discrete thresholds relative to the patient's maximum exercise capacity in order to compute the sensor target rate.

14. (Previously Amended) The method of claim 11 wherein the slope of the rate response curve is adjusted by a specified step amount so as to increase or decrease the responsiveness of the pacemaker in accordance with whether weekly average maximum sensor indicated rate is lesser or greater, respectively, than the sensor target rate.

15. (Previously Amended) A system for operating a rate-adaptive pacemaker wherein measured exertion levels in a patient are mapped to a sensor indicated rate by a rate response curve, comprising:

means for automatically determining the patient's maximum exercise capacity as defined by a long-term maximum exertion level by collecting maximum measured exertion levels over a specified period of time, wherein the rate response curve is defined such that an exertion level corresponding to the patient's maximum exercise capacity would be mapped to a physiologically favorable maximum rate, MAR;

means for limiting the rate mapped by the rate response curve to a specified maximum sensor indicated rate MSR that is independent from the MAR; and,

means for increasing the MSR after a specified time period during which the long-term maximum exertion level is updated.

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16. (Original) The system of claim 15 wherein the MSR is gradually increased to equal the MAR.
17. (Currently Amended) The system of claim 15 further comprising:  
means for collecting daily maximum exertion levels;  
means for periodically updating a long-term ~~maximal~~ maximum exertion level of the patient to equal a maximum among the collected daily maximum exertion levels during the specified time period; and,  
means for adjusting a slope of the rate response curve in order for the updated long-term maximal exertion level to be mapped to the MAR.
18. (Original) The system of claim 17 wherein the collected daily maximum exertion levels are maximums among moving averages of the exertion levels measured during a day.
19. (Previously Amended) The system of claim 17 wherein the rate response curve is a dual-slope curve where the slope changes from a low rate response factor to a high rate response factor at a heart rate breakpoint that is computed as a percentage of the patient's rate reserve.
20. (Previously Amended) The system of claim 19 wherein the rate response curve is adjusted by increasing or decreasing the low rate response factor.
21. (Previously Amended) The system of claim 19 wherein the high rate response factor is adjusted to map the patient's long-term maximum exertion level to the MAR.
22. (Original) The system of claim 19 wherein the slope of the rate response curve is adjusted with the heart rate breakpoint maintained as a fixed percentage of the rate reserve.
23. (Original) The system of claim 19 wherein the slope of the rate response curve is adjusted with the heart rate breakpoint maintained as a dynamic percentage of the rate reserve that changes in accordance with changes in the long-term maximum exertion level.

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24. (Previously Amended) The system of claim 19 wherein a percentage of the patient's rate reserve used to compute the heart rate breakpoint is increased or decreased by the percentage increase or decrease, respectively, in the long-term maximum exertion level as a result of updating.

25. (Original) A processor-readable storage medium having processor-executable instructions for performing the method recited in claim 1.